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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,383	10/10/2000	Gertrud Hoetten	2923-120	7142
6449	7590	10/15/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/684,383

Applicant(s)

HOTTEN ET AL.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment submitted on 8/23/2004 has been entered. Amended claim 29 (8/23/04) and previous claims 24-28 and 30-43 are pending and under consideration by the Examiner.
2. Receipt of applicant's arguments and amendments filed on 8/23/2004 is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 8/23/2004:
 - (i) the rejection of claims 24, 26-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.
4. Applicant's arguments filed on 8/23/04 have been fully considered and were persuasive. The new issues are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-statutory double patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

- 6a. Claim 24(a), (c) is rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8(a), 9 and 10 of prior U.S. Patent No. 6,120,760. This is a double patenting rejection.

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Nucleotides 1-2272 of SEQ ID NO:2 in the U.S. Patent are 100% identical to SEQ ID NO:1 in the instant application.

The 352 amino acids of SEQ ID NO:4 in the U.S. patent are 100% identical to SEQ ID NO:2 in the instant application.

6b. Claims 25 and 29 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 9 of prior U.S. Patent No. 6,120,760. This is a double patenting rejection.

Double-patenting-obviousness-type

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-12 of U.S. Patent No. 6,120,760. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8 of U.S. Patent No. 6,120,760, claims an MP-121 protein of SEQ ID NO:2, and a protein encoded by a nucleotide sequence that hybridizes the DNA encoding SEQ ID NO:2. In instant claim 24, the same protein is claimed under less stringent washing conditions and higher salt hybridizing conditions. Instant claim 24, is generic to claim 8 in the patent and encompasses

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subject matter to which the allowed claims are a species. However, the patented claim is obvious from the instant claim because the patent claim is directed to one specific embodiment encompassed by instant claim 24. The patented product is included in instant claim 24. Similarly the mature protein of claims 24, 29 and 35 include the mature protein of claim 12 of the patent. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a protein as claimed included a protein in the patent, because of the less stringent washing conditions and higher salt hybridizing conditions in the instant case, encompassing the protein species claim in the patent.

Furthermore, with respect to claims 26, 30-32, 37, 39-40, 42, it would have been prima facie obvious to one having ordinary skill in the art to modify the polypeptide of the instant invention such that it includes a homodimeric or a heterodimeric protein (comprising a monomer and a monomer of another protein from the TGF- β family to obtain a chimeric protein) with an increased circulating half-life, and to obtain the known functions and advantages of the proteins in the homodimer or of both the proteins in a heterodimer. Cytokines are well-known in the art as having a short half-life.

Furthermore, with respect to claims 27-28, 33-34, 36, 38, 41, 43, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, to merely admix a carrier with a known protein, and obtaining such does not render the resulting method for producing a pharmaceutical composition patentable if it would have been obvious to formulate the protein with a carrier relative to its art intended use (In re Rosicky 125 USPQ 341). Therefore, the patented claims if infringed upon would also result in infringement of the broad

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claims of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
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September 28, 2004